

## **REMARKS**

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated March 10, 2004 (hereinafter, "the Office Action"). Claims 12-15, 19-21, and 23-30 are pending in the present application upon entry of the present Amendment. The concerns raised by the Examiner in the Office Action are addressed below.

### **I. Interview Summary**

Applicants appreciate the Examiner's participation in a telephonic interview with the Applicants' representative, Shawna Cannon Lemon, on August 23, 2004. During the interview, the Examiner and Applicants' representative discussed cited references, JP 02 096535, the English translation of JP 02 096535 and Bukowski et al. *Blood*. **84(No. 1, Suppl. 1): 129a** (1994) in view of the pending application. The Examiner alleged that the references appear to be directed to the same methods for the same patient population. Applicants provide a response below to address the Examiner's concerns.

### **II. Request for Continued Examination and Supplemental Information Disclosure**

Applicants appreciate the Examiner's indication that the Request for Continued Examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.117(e), has been acknowledged, and the finality of the previous Office Action has been withdrawn in response thereto. Applicants further appreciate the Examiner's indication that the Supplemental Information Disclosure Statement filed September 16, 2003 has been entered.<sup>1</sup>

### **III. Double Patenting Rejection**

#### **A. Claims 12-15, 19-21 and 23-26**

Claims 12-15, 19-21 and 23-26 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over Claims 31-32, 35-38 and 40 of U.S. Patent Application Serial No. 09/525,808<sup>2</sup>.

The '808 application has not issued and none of Claims 31-32, 35-38 and 40 have been allowed. Thus, Applicants do not believe that it is necessary to file a Terminal

<sup>1</sup> The Office Action indicates that the Supplemental Information Disclosure Statement was filed on September 22, 2003).

Disclaimer with this response to overcome this provisional rejection. However, Applicants are prepared to provide a Terminal Disclaimer if it is determined to be necessary upon allowance of the relevant claims. Accordingly, Applicants respectfully request that the provisional rejection of Claims 12-15, 19-21 and 23-26 be withdrawn.

**B. Claims 12, 19 and 26**

Claims 12, 19 and 26 stand rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over Claims 1-4 and 6-7 of U.S. Patent No. 5,922,674. In order to expedite prosecution of the present application, a Terminal Disclaimer executed by Applicants' attorney is filed herewith, whereby any patent term for the present application extending beyond the term of U.S. Patent No. 5,922,674 is disclaimed. Accordingly, Applicants believe this obviousness-type double patenting rejection is overcome, and respectfully request its withdrawal.

**IV. Claim Rejections Under 35 U.S.C. § 102**

Claims 12, 19, 20 and 26 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bukowski et al. *Blood*. **84(No. 1, Suppl. 1): 129a** (1994) (hereinafter, "Bukowski et al."). Claims 12, 15, 19, 20, 21 and 24-26 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by JP 02 096535. Applicants respectfully disagree.

In an effort to expedite prosecution of the claims in the pending application, Applicants have amended Claim 12 to recite as follows:

12. A method of treating a solid vascularized tumor in a subject in need of such treatment, comprising administering cisplatin in conjunction with erythropoietin, wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial growth associated with administration of said cisplatin **and wherein said subject is afflicted with or at risk of developing a solid vascularized tumor selected from cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx.**

Applicants have further amended Claim 21 to recite as follows:

A method of treating a solid vascularized tumor in a subject in need of such treatment, comprising administering cisplatin in conjunction with erythropoietin;  
wherein said erythropoietin is administered in an amount of from about

<sup>2</sup> Attorney Docket No. 5218-39C.

750 Units per kilogram to about 2,000 Units per kilogram **and said subject is afflicted with or at risk of developing a solid vascularized tumor selected from cerebellar hemangioblastoma, ductal carcinoma of the breast, or squamous cell cancer of the larynx.**

"Anticipation under 35 U.S.C. § 102 requires the disclosure of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (*relying on Electro Med. Sys. S.A. v. Cooper Life Scis.*, 32 USPQ2d 1017, 1019 (Fed Cir. 1994)). Moreover, the cited references must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Consequently, the cited reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

Applicants respectfully submit that neither Bukowski et al. nor JP 02 096535 disclose each and every recitation of amended Claim 12 or amended Claim 21 as required to establish anticipation under 35 U.S.C. § 102. More specifically, neither reference discloses 1) a method of treating a solid vascularized tumor as recited in amended Claim 12 wherein the subject is afflicted with or at risk of developing a solid vascularized tumor selected from cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx, or 2) a method of treatment comprising the dosage administration of erythropoietin as recited in amended Claim 21. Thus, the recitations of amended Claim 12 are directed to a **distinct patient population** than the patient population disclosed in the cited references. Additionally, the recitations of amended Claim 21 are directed to a **specific dosage administration** of erythropoietin in a **distinct patient population** than that disclosed in the cited references. In contrast, the cited references are directed to Phase IV evaluation of clinical outcomes of PROCRT<sup>®</sup> in anemic cancer patients receiving chemotherapy (Bukowski et al.) and therapeutic agents for anemia caused from bone marrow dysfunction (JP 02 096535). Thus, the cited references do not teach a method of treating specific solid vascularized tumors selected from cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx, and further fail to teach a specific dosage administration of erythropoietin with respect to such treatment.

Accordingly, Applicants respectfully submit that amended Claim 12 and amended Claim 21, and claims that depend therefrom, are not obvious under 35 U.S.C. § 102 in view of the cited references, and respectfully request that this rejection be withdrawn.

**V. New Claims 27-30 Are Patentable Over the Cited References**

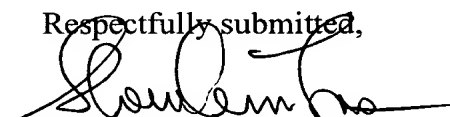
Applicants have added new Claims 27-30. Support for new Claims 27-30 can be found in the specification and claims as originally filed. In particular, the Examiner is directed to page 5, lines 14-20 of the present application. Applicants respectfully submit that none of the cited references, alone or in combination, teach or suggest methods of treating a condition associated with abnormal angiogenesis as recited in new Claim 27. Consequently, Applicants respectfully request entry and allowance of new Claims 27-30.

**Conclusion**

Applicants respectfully submit that, for the reasons discussed above, the references cited in the present rejections do not disclose or suggest the present invention as claimed. Accordingly, Applicants respectfully request allowance of all the pending claims and passing this application to issue.

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



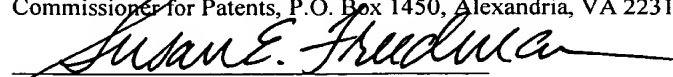
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Susan E. Freedman